Cricothyroidotomy Device in 10 Cadavers" and "Evaluation of a New Cricothyroidotomy Kit Utilizing a Built-in Veress Needle Trocar Technology". These articles should provide the examiner with a sense of the inventiveness and differences between the device of the instant invention and those of the prior art, and more particularly point out the fact that the device of the instant invention provides for a single step introduction of a cricothyroidotomy tube over an integral obturator/dilator through the cricothyroid membrane of a patient. Such could not be done by any of the cited prior art devices.

In view of such objective evidence, the examiner is respectfully requested to reconsider the application and pass the case to issue at an early date.

Respectfully submitted,

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Evaluation of a New Emergency Cricothyroidotomy Device in 10 Cadavers

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Introduction

A new Emergency Cricothyroidotomy Device (Smiths Medical,UK) has been developed in conjunction with the UK Military Special Forces for emergency airway access in the field. The device allows a single step introduction of a 6mm I.D. cuffed, 90mm long cricothyroidotomy tube over an integral obturator/dilator and allows spontaneous and mechanical ventilation. Confirmation of both entry into the trachea through the cricothyroid membrane and safety during insertion is achieved by the use of a Veress needle with a blunt, spring loaded, stylet which protrudes beyond the sharp needle tip, preventing trauma to the posterior tracheal wall. The stylet is pushed back to expose the cutting edge of the needle during insertion through tissues. A red indicator is clearly visible in the Veress needle hub on insertion but disappears once the needle tip has correctly entered the trachea.
This study aimed to assess the performance of the device, ease of insertion, confirmation of Veress needle red indicator use, time for insertion and assessment of posterior tracheal wall trauma.

Method

The study was undertaken at the Medical Education & Research Institute, Memphis, USA. All cadavers were donated to the institute with donor signed consent forms.
Each cadaver had a flexible fibre-optic bronchoscope placed at the level of the vocal cords to observe for posterior tracheal wall trauma. Time from skin incision to tube flange placement at the neck was recorded. Identification of anatomical landmarks, location of cricothyroid membrane, insertion force and overall assessment of the procedure was documented. A 5.3mm catheter and a fibre-optic bronchoscope were passed down the internal lumen of each tube to confirm patency and no kinking of the tube. Following cricothyroidotomy tube removal the trachea was examined for signs of posterior tracheal wall injury down to the carina.

Results

The Emergency Cricothyroidotomy Device was successfully inserted in all 10 cadavers. Mean (range) Age; years 74.8 (55-89), Weight; Kg 77 (43-120), Height; m 1.75 (1.58-1.93), Time to insertion; seconds 49 (30-89)

Identification of anatomical landmarks	Easy	6	Moderate	3	Difficult	1
Location of cricothyroid membrane	Superficial	6	Intermediate	4	Deep	0
Insertion Force	Easy	3	Moderate	7	Difficult	0
Overall Assessment	Easy	9	Moderate	0	Difficult	1

In all 10 cadavers the cricothyroid membrane was penetrated easily, the red indicator confirmed entry into the trachea and contact with the posterior cricoid wall. The device was easy to hold, direct, and angle caudally. In all cadavers the tube slid off the obturator easily, the obturator was easy to remove and the flange of the device located on the neck satisfactorily.
The passage of a catheter and fibre-optic bronchoscope confirmed tube patency and no kinking in all tubes.
For the first two cadavers minor/acceptable and major/acceptable trauma occurred to the posterior cricoid cartilage. In both of these insertions the investigator was observing the video monitor and not the red indicator in the needle hub showing the posterior cricoid cartilage had been reached. Similarly for the first and third insertion contact was made with the posterior tracheal wall (red indicator). None of the cadavers showed any trauma to the posterior tracheal wall.

Discussion

The overall assessment of the device showed easy insertion in 9 cadavers and a difficult insertion in 1 due to difficult identification of anatomical landmarks. The device is quick and easy to insert with a mean insertion time of 49 seconds.
The only problems arose in the first 3 cadavers with trauma to the cricoid cartilage and contact with the posterior tracheal wall although no damage to the posterior tracheal wall was identified. This may represent a short (2-3 insertions) learning curve as the subsequent 7 cases were uneventful.

Conclusion

The Emergency Cricothyroidotomy Device was successfully inserted in all 10 cadavers and would be an excellent device for use when an emergency cricothyroidotomy is indicated. An airway was achieved in less than 1 minute with no trauma to the posterior tracheal wall. A short learning curve (2-3 insertions) appears to exist.

Evaluation of a New Cricothyoidotomy Kit Utilizing Built-in Veress Needle Trocar Technology

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Introduction:

One option toward securing the airway in a "cannot ventilate/cannot intubate" situation, when other modalities have failed, is to obtain surgical access to the airway. A new cricothyroidotomy kit (Portex Emergency Cricothyroidotomy Kit, Smiths Medical, Hythe, UK) utilizes Veress needle technology to facilitate introduction of the dilator and endotracheal tube through the cricothyroid membrane in a single maneuver. This product is designed with a built in "red flag indicator" which retracts upon penetration of the cricothyroid membrane indicating intra-tracheal position and reappears if the blunt portion of the Veress needle tip comes into contact with the opposing tracheal wall, potentially minimizing the chance of injury to the vulnerable soft posterior membranous trachea. The safety and effectiveness of this new needle/dilator design is the subject of this study.

Methods:

Experienced airway managers with anesthesia, emergency medicine and trauma surgery backgrounds were provided instruction with the preassembled kit via a DVD based video demonstration followed by insertion practice on a manikin specifically designed for performing surgical airway access via the cricothyroid membrane. Following this training, the operators then performed insertion of the surgical airway (6.0mm, I.D.) into partially thawed (non-fresh) cadavers. Pathologic evaluation of the hyoid-cricotracheal complex was performed following the procedure, assessing for airway position and the presence or absence of associated injury. Successful airway insertions were defined as central intralumenal positioning of the device in the airway with a patent distal tip. Successful insertions were further classified as non-injurious and injurious depending on presence or absence of associated tracheal or paratracheal injury.

Results:

33/40 (83%) had successful insertion of the PCK airway. Of these 33 successful insertions, 24/33 (73%) were non-injurious (19 no complication, 3 abrasions ≤1.5cm, 2 abrasions ≥1.6cm). 9/33 (27%) were injurious (4 lacerations ≤1.5cm, lacerations, 3 lacerations ≥1.6cm, one first tracheal ring injury*, and one thyroid

cartilage fracture**). Seven cases of insertion failure were observed. 4 of 7 cases correctly passed through the cricothyroid membrane but resulted in a misplaced distal tip of the endotracheal tube penetrating the opposite wall of the trachea (3 posterior, 1 lateral). 3 of the 7 insertion failures never penetrated the cricothyroid membrane and were entirely extra-tracheal (2 paratracheal, 1 subcutaneous, 1 ineffective penetration of tissues***). Timeliness of insertion was quantified by reviewing video footage of the procedures and timing from the time the knife was grasped for making the skin incision to the beginning of the first ventilation following insertion. Insertion times ranged from 20 -122 seconds with a mean insertion time of 42.3 seconds.

* Introduction resulted in a thyroid cartilage fracture. Poor external landmark definition reported by practitioner.
** Airway inadvertently placed via the cricotracheal membrane lead to fracture of the 1st tracheal ring. Poor external landmark definition reported by practitioner.
***Marked deformity of cadaver and postmortem lividity made penetration of tissues impossible. Procedure aborted.

Conclusion:

The PCK airway system allowed rapid and expeditious placement of an endotracheal surgical airway in the majority of insertions (83%). This success rate is comparable or better than other previous reports utilizing pathologic analysis for confirmation of tube placement and identification of associated injury in surgical crycothyroidotomy[1, 2]. Insertion required no significant assembly and was performed in one rapid fluid motion facilitating ease of timely placement. However, despite its innovative design, injuries and potentially disastrous airway placement difficulties were not completely avoided. Further study of this system in a live animal model may provide a more realistic and accurate appraisal of PCK airway's performance in the clinical setting and appears indicated prior to any widespread application or abandonment of this new and innovative technology.

References:

[1]Schaumann N et al., Evaluation of Seldinger Technique Emergency Cricothyroidotomy versus Standard Surgical Cricothyroidotomy in 200 Cadavers. Anesthesiology, Jan 2005; 102(1):7-11.

[2]Eisenburger P, Comparison of conventional surgical versus Seldinger technique emergency cricothyroidotomy performed by inexperienced clinicians. Anesthesiology, Mar 2000; 92(3):687-90.